



DEPARTMENT OF NEUROSURGERY  
Henry Ford Hospital & Medical Centers

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**Mark L. Rosenblum, MD**  
Chair  
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RE: Docket No. 97N-484S

To Whom It May Concern:

As a practicing neurosurgeon, I am writing to comment on the proposed regulation appearing in the September 30, 1999, issue of the Federal Register regarding bone banks. Currently, the bone banks provide bone tissue for which the FDA does regulate the safety. These bone grafts are used for a significant number of procedures on the cervical spine as well as other areas of the spine requiring reconstructive work as well as treatment for conditions like cervical spondylosis, tumors and infections, etc.

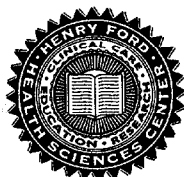
I have not come across any problems from the tissues available through bone banks so far; and therefore, the present system of safety regulation would seem to be quite appropriate and adequate. It should not be required to be regulated as a medical device which would increase the cost of the product significantly and also could constrain the availability of the materials, thus, significantly impairing our ability to provide the necessary care for the patients.

Sincerely,

Ghaus M. Malik, MD  
Vice Chairman  
Department of Neurosurgery

GMM/dmp

A Member of Henry Ford Medical Group



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